REMARKS

Claims 1 to 28 are pending in this application. Claims 1 to 24 and 28 are allowed. Claim 25 are rejected. Claims 26 and 27 are objected to. Applicants are herein amending claim 25. Applicants acknowledge the Examiner's comments regarding the Information Disclosure Statement and are addressing same in a separate paper.

Claim Amendments

Applicants are herein amending claim 25, without prejudice or disclaimer, to specify that the compounds of the Formula I are useful in methods of treating a subject suffering from anorexia nervosa and bulimia nervosa rather than eating disorders, and premature ejaculation rather than sexual dysfunction. Applicants submit that the amendment to claim 25 does not introduce new matter. Support for the amendment may be found, *inter alia*, on page 39, paragraph [0038]. Applicants reserve the right to pursue the cancelled subject matter in one or more continuing applications.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 25 is rejected as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. While applicants traverse the rejection.

The Office Action suggests that the term "sexual dysfunction" encompasses infertility and sexually transmitted diseases. Applicants submit that the definition proposed by the Office Action is contrary to the understanding of those who would use such terminology in the course of researching, diagnosing, or treating the conditions associated therewith. "Sexual dysfunction" commonly refers to a problem during any phase of the male or female sexual response cycle that prevents the individual or couple from experiencing

satisfaction from the sexual activity. It does not traditionally encompass infertility and sexually transmitted diseases.

Since it is understood by those skilled in the art that mediation of serotonin uptake via administration of therapeutic pharmaceutical compositions can provide effective treatment for sexual dysfunction (for example, paroxetine and other SSRIs have been used to effectively treat certain forms of sexual dysfunction; *see* Waldinger MD, Olivier B. *Utility of selective serotonin reuptake inhibitors in premature ejaculation. Curr Opin Investig Drugs.* 2004 Jul;5(7):743-7; attached), Applicants have provided sufficient enablement for the treatment of this class of medical conditions.

While applicants traverse the rejection for the reasons stated above, applicants are amending claim 25 to replace the term "eating disorders" with "anorexia nervosa" and nonetheless bulimia nervosa" and the term "sexual dysfunction" with "premature ejaculation," solely to expedite prosecution of the application.

Accordingly, applicants request that the rejection of claim 25 be withdrawn.

Claim Objections

Claims 26 and 27 are objected to as being dependent upon a rejected base claim. Applicants submit that claim 25, as amended, is allowable. Accordingly, applicants request withdrawal of the objection to claims 26 and 27.

Conclusions

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference

would expedite prosecution of this application, please contact the undersigned at 215-557-3861.

Date: January 21, 2005

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Curr Opin Investig Drugs. 2004 Jul;5(7):743-7.

Utility of selective serotonin reuptake inhibitors in premature ejaculation.

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The introduction of selective serotonin reuptake inhibitors (SSRIs) has revolutionized our understanding of the treatment of premature ejaculation. Lifelong premature ejaculation may be a neurobiological phenomenon, namely part of a biological variability of the intravaginal ejaculation latency time in men. Animal studies support this view, and an animal model for premature and delayed ejaculation has recently been developed. It is proposed that drug treatment of premature ejaculation should consist of 5-hydroxytryptamine (5-HT)2c receptor stimulation and/or 5-HT1A receptor inhibition. A meta-analysis of 35 daily treatment studies with selective serotonin reuptake inhibitors (SSRIs) and clomipramine demonstrated comparable efficacy of clomipramine with the SSRIs sertraline and fluoxetine in delaying ejaculation, whereas the efficacy of the SSRI paroxetine was greater than all other SSRIs and clomipramine. It is postulated that acute treatment with SSRIs, including those with short half-lives, will not produce an ejaculation delay equivalent to that induced by daily treatment of SSRIs.

Publication Types:

- Review
- Review, Tutorial

PMID: 15298071 [PubMed - indexed for MEDLINE]